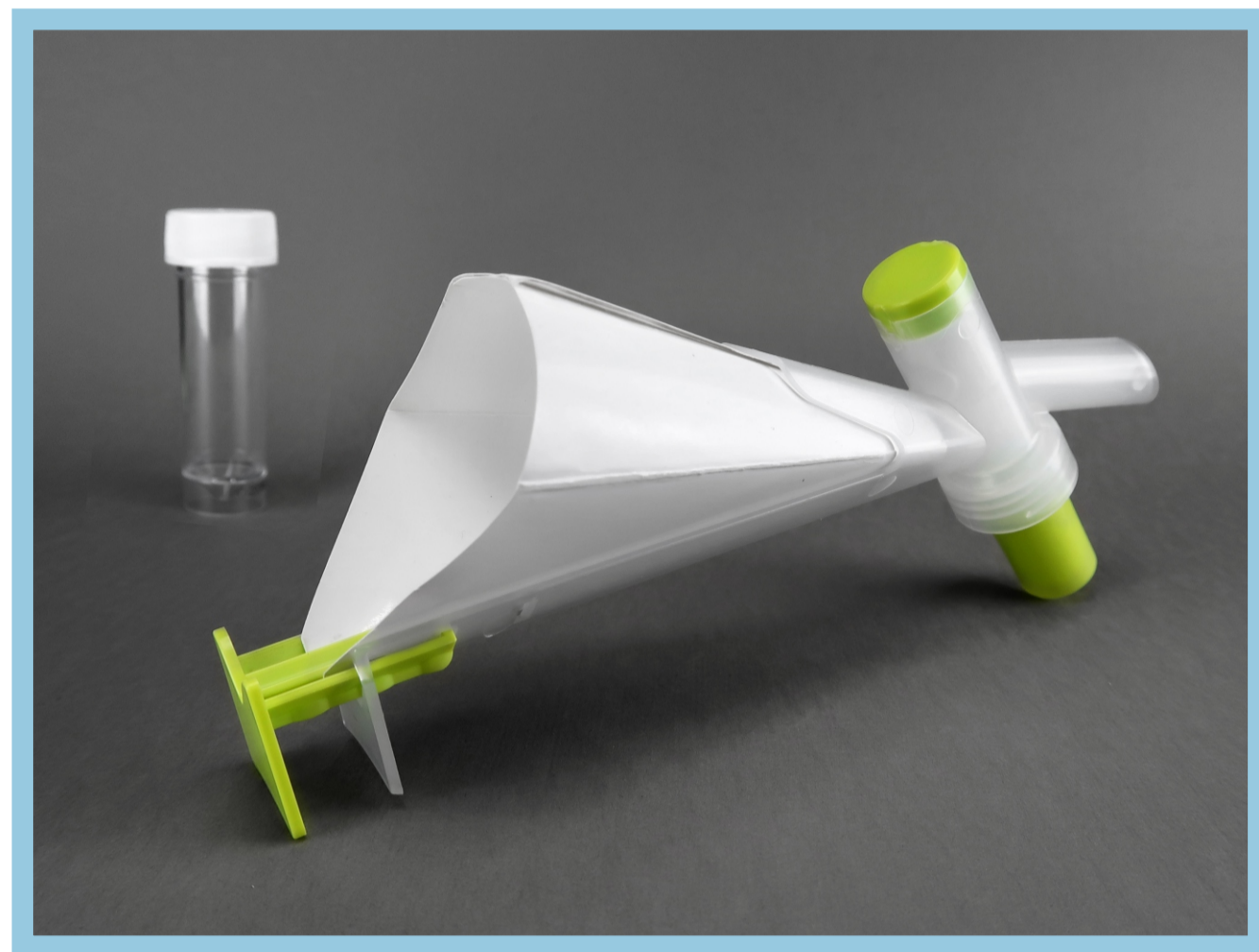


BACKGROUND & OBJECTIVES

The aim of this study was to compare the usability of the previous version (CP-2000) of the Colli-Pee® to the current improved device (FV-5000), in which the funnel material was changed from cardboard to polypropylene, the number of components was reduced from 8 to 4 and the thread of the tube was changed from an outer to an inner thread. These changes were performed to make the device easier to assemble and use in general.



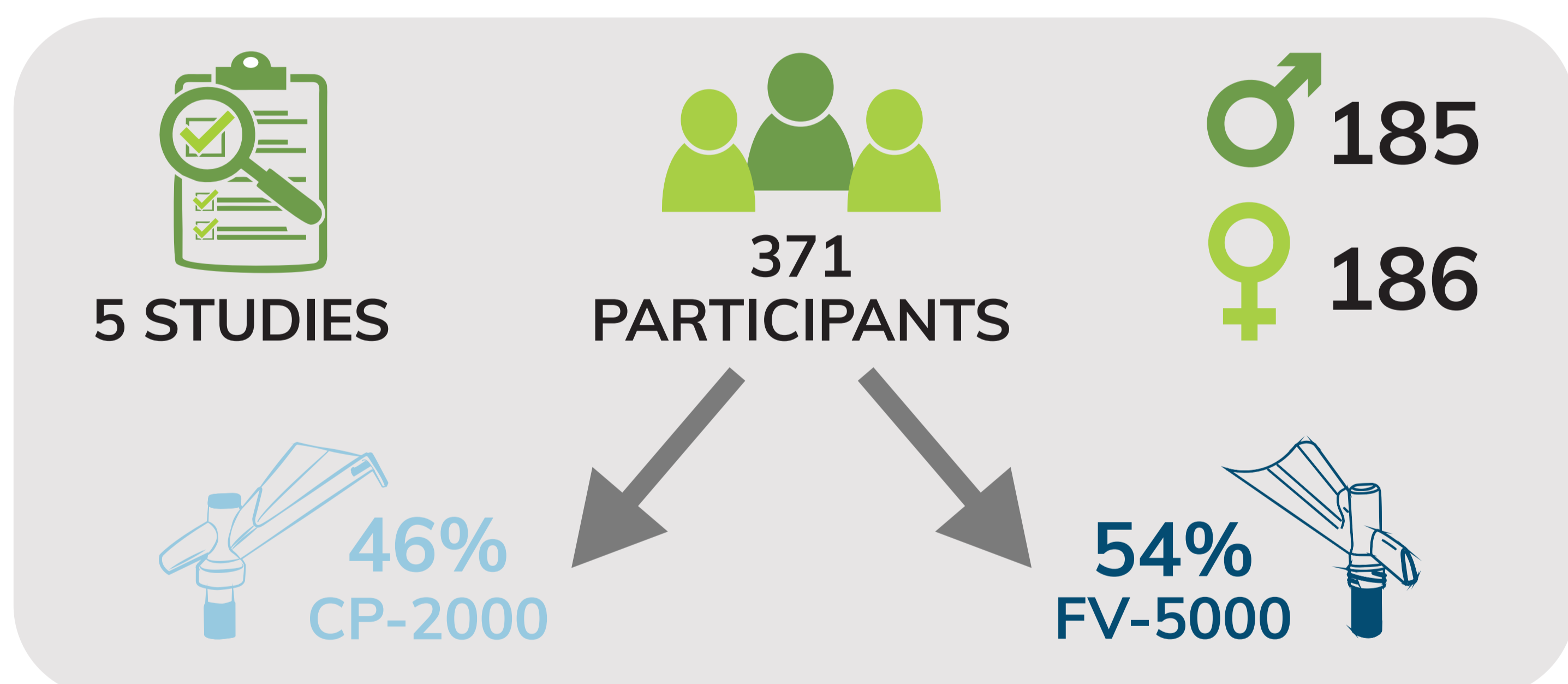
CP-2000



FV-5000

METHODS

Usability data collected from five clinical studies was used. For each study, a questionnaire on usability consisting of yes-no, open and 5-point Likert scale (very unclear to very clear) questions was completed by the participants using one of both devices. Fisher Exact Test was used to compare usability data from both versions of the Colli-Pee®.



RESULTS

Among a total of 371 participants (185 male, 186 female; age range 17-70 years old), 46% used CP-2000 and 54% FV-5000. The majority found Colli-Pee® very easy (70%) and easy (21%) to use, 7% found it moderately easy to use and a minority found it unclear (1%) to very unclear (1%), no significant difference in easiness to use between versions was observed ($p=0.445$). The FV-5000 version had less urine spillage during collection: 8% compared to 23% for the CP-2000 ($p=0.070$). Some spillage after collection was present in both devices (11%, $p=1.000$). The instructions for use were found to be clearer and easier for FV-5000 compared to CP-2000 (90% vs 65%, $p=0.006$). 92% of the subjects would like to use Colli-Pee® as sample method for screening purposes (92%, $p=1.000$) and would recommend it to others (CP-2000: 92%, FV-5000: 100%; $p=0.175$). Packaging and recyclability raised a few concerns for both device versions, but the Colli-Pee® exists of polypropylene and high-density polyethylene which can be recycled or incinerated into energy.

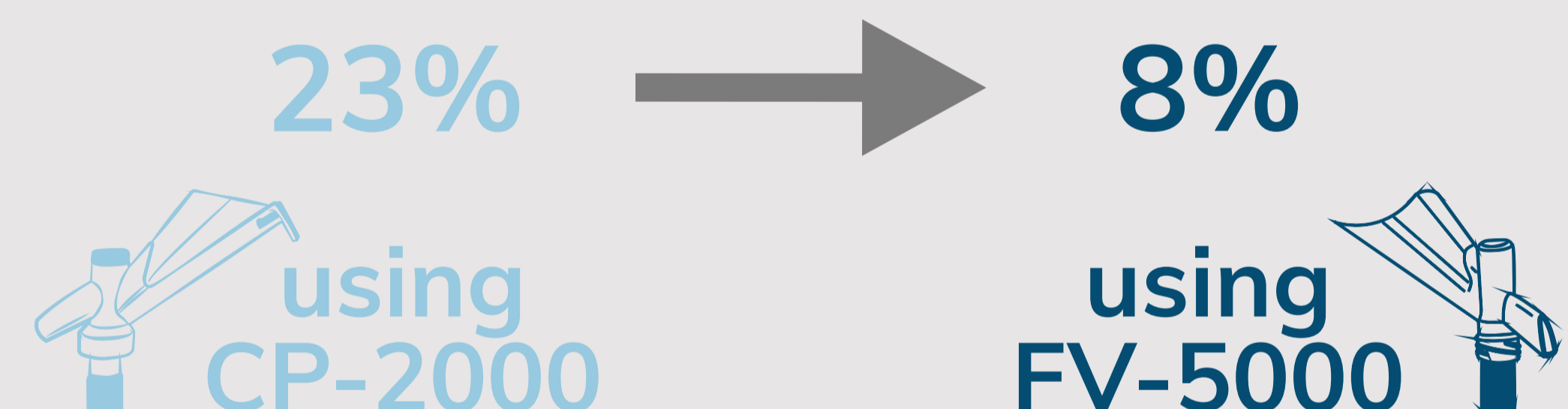
Colli-Pee® (CP-2000 and FV-5000)

- + Suitable for home use
- + Suitable for transportation by regular mail
- + Hygienic
- + Convenient
- + Women friendly
- + Good urine collection system
- + No need to interrupt the urine flow

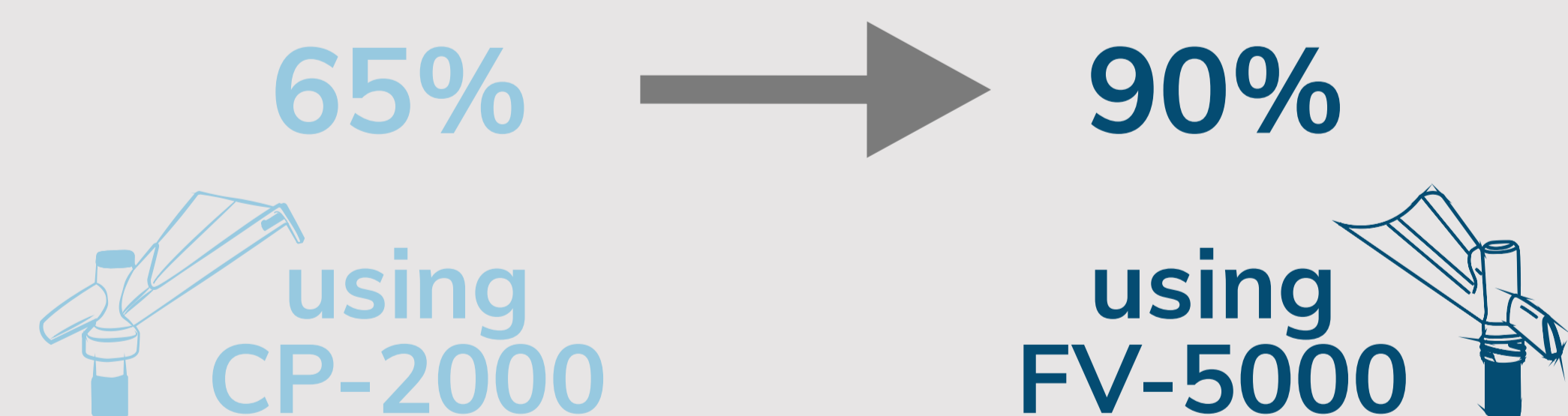
91%
find Colli-Pee®
'easy' or 'very
easy' to use

92%
would like to
use Colli-Pee®
for screening
purposes

Reduced spillage during collection



Instructions for use clearer and easier



CONCLUSION

Usability of the Colli-Pee® device was valued as very good and design updates were shown effective through easier assembly of the device before use and reduced spillage of urine during collection. In addition, the Colli-Pee® can be sent by regular mail, making it an easy device suitable for home-based screening purposes. Biodegradable materials are under evaluation.